

## Part I Overview Information

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Department of Health and Human Services

### Participating Organizations

National Institutes of Health (NIH) (<http://www.nih.gov>)

### Components of Participating Organizations

National Institute on Aging (NIA), (<http://www.nia.nih.gov/>)

National Institute on Alcohol Abuse and Alcoholism (NIAAA), (<http://www.niaaa.nih.gov/>)

National Institute of Allergy and Infectious Diseases (NIAID), (<http://www.niaid.nih.gov/>)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS),  
(<http://www.niams.nih.gov/>)

National Institute of Biomedical Imaging and Bioengineering (NIBIB),  
(<http://www.nibib.nih.gov/>)

National Cancer Institute (NCI), (<http://www.nci.nih.gov/>)

National Institute of Child Health and Human Development (NICHD),  
(<http://www.nichd.nih.gov/>)

National Center for Complementary and Alternative Medicine (NCCAM),  
(<http://www.nccam.nih.gov/>)

National Institute on Deafness and Other Communication Disorders (NIDCD),  
(<http://www.nidcd.nih.gov/>)

National Institute of Dental and Craniofacial Research (NIDCR), (<http://www.nidcr.nih.gov/>)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK),  
(<http://www.niddk.nih.gov/>)

National Institute on Drug Abuse (NIDA), (<http://www.nida.nih.gov/>)

National Institute of Environmental Health Sciences (NIEHS), (<http://www.niehs.nih.gov/>)

National Eye Institute (NEI), (<http://www.nei.nih.gov/>)

National Institute of General Medical Sciences (NIGMS), (<http://www.nigms.nih.gov/>)

National Heart, Lung, and Blood Institute (NHLBI), (<http://www.nhlbi.nih.gov/>)

National Human Genome Research Institute (NHGRI), (<http://www.nhgri.nih.gov/>)

National Institute of Mental Health (NIMH), (<http://www.nimh.nih.gov/>)

National Institute of Neurological Disorders and Stroke (NINDS), (<http://www.ninds.nih.gov/>)

National Institute of Nursing Research (NINR), (<http://www.ninr.nih.gov/>)

National Library of Medicine (NLM), (<http://www.nlm.nih.gov/>)

National Center for Research Resources (NCRR), (<http://www.ncrr.nih.gov/>)

Title: Research Project Grant (Parent R01)

Announcement Type

New

**Update:** The following update relating to this announcement has been issued:

- January 25, 2008 - (This PA Runs Parallel with PAR-08-080)
- September 17, 2007 - Expiration Date adjusted to accommodate recent changes to standing submission deadlines, per NOT-OD-07-093.
- November 21, 2006 (NOT-LM-06-008) - See Notice NOT-LM-06-008 for notice of replacement of PA-06-094.
- November 22, 2006 (NOT-AI-07-011) - See Notice NOT-AI-07-011 for notice of R01 application only through PA-07-070.

**Note:** See information on all Parent Announcements for Unsolicited or Investigator-Initiated applications.

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

**APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.**

This FOA must be read in conjunction with the application guidelines included with this announcement in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four weeks prior to the grant submission date. See Section IV.

Program Announcement (PA) Number: PA-07-070

This is the Program Announcement Number

Apply for Grant Electronically

A compatible version of Adobe Reader is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <http://grants.gov/CustomerSupport>.

Catalog of Federal Domestic Assistance Number(s)

93.113, 93.114, 93.115, 93.121, 93.143, 93.172, 93.173, 93.213, 93.233, 93.242, 93.273, 93.279, 93.286, 93.361, 93.389, 93.393, 93.394, 93.395, 93.396, 93.399, 93.837, 93.838, 93.839, 93.846, 93.847, 93.848, 93.849, 93.853, 93.855, 93.856, 93.859, 93.865, 93.866, 93.867, 93.879

Key Dates

Release/Posted Date: November 20, 2006

Opening Date: January 5, 2007 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): Not Applicable

**NOTE: On time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization).**

Application Submission/Receipt Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm>

AIDS Application Submission/Receipt Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS>

Peer Review Date(s): Standard dates apply, please see

Standard Application Dates Apply



<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

Council Review Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

Earliest Anticipated Start Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

Additional Information To Be Available Date (URL Activation Date): Not Applicable

Expiration Date: January 3, 2010 (now January 8, 2010 per NOT-OD-07-093)

Due Dates for E.O. 12372

PA Expiration Date!!

Not Applicable

Additional Overview Content

Executive Summary

This is the area that has all the general information regarding the funding, support, limits, etc.

- **Purpose.** The Research Project Grant (R01) is an award made to an institution/organization to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in areas representing the specific interests and competencies of the investigator(s). The R01 research plan proposed by the applicant institution/organization must be related to the stated program interests of one or more of the NIH Institutes and Centers (ICs) based on descriptions of their programs. All research project grant applications described in this announcement will be assigned to NIH ICs according to standard Public Health Service (PHS) referral guidelines and specific program interests. Investigators are encouraged to consult the participating NIH ICs and their Web sites (see <http://www.nih.gov/icd>).
- **Mechanism of Support.** This Funding Opportunity Announcement (FOA) will use the NIH Research Project Grant (R01) award mechanism.
- **Funds Available and Anticipated Number of Awards.** Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the numbers, quality, duration, and costs of the applications selected for award.
- **Eligible Institutions/Organizations.** Public/State Controlled Institution of Higher Education; Private Institution of Higher Education; Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education); Nonprofit without 501(c)(3) IRS Status (Other than Institution of Higher Education); Small Business; For-Profit Organization (Other than Small Business); State Government; U.S. Territory or Possession; Indian/Native American Tribal Government (Federally Recognized); Indian/Native American Tribal Government (Other than Federally Recognized); Indian/Native American Tribally Designated Organization; Non-domestic (non-U.S.) Entity (Foreign Organization); Hispanic-serving Institution; Historically Black Colleges and Universities (HBCUs); Tribally Controlled Colleges and Universities (TCCUs); Alaska Native and Native Hawaiian Serving Institutions; Regional Organization; Other(s): Eligible agencies of the Federal government; Faith-based or community based organizations.

- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
- **Number of Applications.** Applicants may submit more than one application, provided each application is scientifically distinct.
- **Renewals and Resubmissions.** Grants can be renewed by competing for additional project periods. Applicants may submit a “resubmission” application, but such application must include an “Introduction” addressing the previous peer review critique (Summary Statement).
- **Number of PDs/PIs.** More than one PD/PI, or multiple PDs/PIs, may be designated on the application.
- **Application Materials.** See [Section IV.1](#) for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these web sites:
  - SF424 (R&R) Application and Electronic Submission Information: <http://grants.nih.gov/grants/funding/424/index.htm>
  - General information on Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>
- **Hearing Impaired.** Telecommunications for the hearing impaired is available at: TTY 301-451-0088.

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### Part II - Full Text of Announcement

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#### Section I. Funding Opportunity Description

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##### 1. Research Objectives

The Research Project Grant (R01) is an award to support a discrete, specified, circumscribed project to be performed by named Project Directors/Principal Investigators (PDs/PIs) in areas representing the investigators' specific interests and competencies, based on the mission of the NIH. The R01 is the original and historically the oldest grant mechanism used by the NIH to support health-related research and development.

The NIH awards R01 grants to institutions/organizations of all types. This mechanism allows the PDs/PIs to define the scientific focus or objective of the research based on particular areas of interest and competence. Although the PDs/PIs write the grant application and are responsible for conducting and supervising the research, the actual applicant is the research institution/organization.

Research grant applications are assigned to an NIH IC based on receipt and referral guidelines and many applications are assigned to multiple ICs with related research interests.

Each IC maintains a Web site with funding opportunities and areas of interest. Contact with an IC representative may help focus the research plan based on an understanding of the mission of the IC. For specific information about the mission of each NIH IC, see <http://www.nih.gov/icd>, which provides a brief summary of the research interests in each IC and access to individual IC home pages.

See [Section VIII, Other Information - Required Federal Citations](#), for policies related to this announcement.

## Section II. Award Information

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### 1. Mechanism of Support

This Funding Opportunity Announcement (FOA) will use the Research Project Grant (R01) award mechanism.

The applicant will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses “Just-in-Time” information concepts. It also uses the modular as well as the non-modular budget formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>).

Specifically, if you are a U.S. organization and are submitting an application with direct costs in each year of \$250,000 or less (excluding consortium Facilities and Administrative [F&A] costs), use the PHS398 Modular Budget component provided in the SF424 (R&R) Application Package and SF424 (R&R) Application Guide (see specifically Section 5.4, “Modular Budget Component,” of the Application Guide).

U.S. applicants requesting more than \$250,000 in annual direct costs and all foreign applicants must complete and submit detailed budget requests using the Research & Related Budget component found in the application package for this FOA. See [NOT-OD-06-096](#), August 23, 2006.

### 2. Funds Available

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the Institutes and Centers (ICs) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made in response to this FOA.

F&A costs requested by consortium participants are not included in the direct cost limitation. See [NOT-OD-05-004](#), November 2, 2004.

### Section III. Eligibility Information

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#### 1. Eligible Applicants

##### 1.A. Eligible Institutions

You may submit an application(s) if your institution/organization has any of the following characteristics:

- Public/State Controlled Institution of Higher Education
- Private Institution of Higher Education
- Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Nonprofit without 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Small Business
- For-Profit Organization (Other than Small Business)
- State Government
- U.S. Territory or Possession
- Indian/Native American Tribal Government (Federally Recognized)
- Indian/Native American Tribal Government (Other than Federally Recognized)
- Indian/Native American Tribally Designated Organization
- Non-domestic (non-U.S.) Entity (Foreign Organization)
- Hispanic-serving Institution
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Regional Organization
- Other(s): Eligible agencies of the Federal government; Faith-based or community based organizations.

##### 1.B. Eligible Individuals

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

More than one PD/PI, or multiple PDs/PIs, may be designated on the application for projects that require a “team science” approach that clearly does not fit the single-PD/PI model. Additional information on the implementation plans and policies and procedures to formally allow more than one PD/PI on individual research projects is available at [http://grants.nih.gov/grants/multi\\_pi](http://grants.nih.gov/grants/multi_pi). All PDs/PIs must be registered in the NIH eRA Commons prior to the submission of the application (see <http://era.nih.gov/ElectronicReceipt/preparing.htm> for instructions).

The decision of whether to apply for a single PD/PI or multiple PD/PI grant is the responsibility of the investigators and applicant organizations and should be determined by the scientific goals of the project. Applications for multiple PD/PI grants will require additional information, as outlined in the instructions below. The NIH review criteria for approach, investigators, and environment have been modified to accommodate applications involving either a single PD/PI or multiple PDs/PIs as indicated below. When considering multiple PDs/PIs, please be aware that the structure and governance of the PD/PI leadership team as well as the knowledge, skills and experience of the individual PD/PIs will be factored into the assessment of the overall scientific merit of the application. Multiple PDs/PIs on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the grantee organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. For further information on multiple PDs/PIs, please see [http://grants.nih.gov/grants/multi\\_pi](http://grants.nih.gov/grants/multi_pi).

## 2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current [NIH Grants Policy Statement](#).

## 3. Other-Special Eligibility Criteria

Applicants may submit more than one application, provided each application is scientifically distinct.

## Section IV. Application and Submission Information

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To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, link to [http://www.grants.gov/applicants/apply\\_for\\_grants.jsp](http://www.grants.gov/applicants/apply_for_grants.jsp) and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at both:

- Grants.gov ([http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp)) and
- eRA Commons (<http://era.nih.gov/ElectronicReceipt/preparing.htm>)

PDs/PIs should work with their institutions/organizations to make sure they are registered in the eRA Commons.

Several additional separate actions are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in [Grants.gov/Get Registered](#)

- Your organization will need to obtain a [Data Universal Number System \(DUNS\) number](#) and register with the [Central Contractor Registration \(CCR\)](#) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:  
[Grants.gov Customer Support](#)  
Contact Center Phone: 800-518-4726  
Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time  
Email [support@grants.gov](mailto:support@grants.gov)

2) Organizational/Institutional Registration in the eRA Commons

- To find out if an organization is already Commons-registered, see the "[List of Grantee Organizations Registered in NIH eRA Commons.](#)"
- Direct questions regarding the Commons registration to:  
eRA Commons Help Desk  
Phone: 301-402-7469 or 866-504-9552 (Toll Free)  
TTY: 301-451-5939  
Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time  
Email [commons@od.nih.gov](mailto:commons@od.nih.gov)

3) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer to the [NIH eRA Commons System \(COM\) Users Guide](#).

- The individual(s) designated as PDs/PIs on the application must also be registered in the NIH eRA Commons. In the case of multiple PDs/PIs, all PDs/PIs must be registered **and be assigned the PI role** in the eRA Commons prior to the submission of the application.

PI must have Account set up in eRA Commons prior to Submission

- Each PD/PI must hold a PD/PI account in the Commons. Applicants should not share a Commons account for both an Authorized Organization Representative/Signing Official (AOR/SO) role and a PD/PI role; however, if they have both a PD/PI role and an Internet Assisted Review (IAR) role, both roles should exist under one Commons account.
- When multiple PDs/Pis are proposed, all PDs/Pis at the applicant organization must be affiliated with that organization. PDs/Pis located at another institution need not be affiliated with the applicant organization, but must be affiliated with their own organization to be able to access the Commons.
- This registration/affiliation must be done by the AOR/SO or their designee who is already registered in the Commons.

Both the PD/PI(s) and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Note that if a PD/PI is also an NIH peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

Several of the steps of the registration process could take four weeks or more. Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered in both [Grants.gov](http://Grants.gov) and the [Commons](#). The NIH will accept electronic applications only from organizations that have completed all necessary registrations.

## 1. Request Application Information

Applicants must download the SF424 (R&R) application forms and the SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](http://Grants.gov/Apply).

Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA), although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact GrantsInfo: Telephone 301-435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

Telecommunications for the hearing impaired: TTY 301-451-0088.

## 2. Content and Form of Application Submission

Prepare all applications using the SF424 (R & R) application forms and in accordance with the SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](http://Grants.gov/Apply).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to NIH. There are fields within the SF424 (R&R) application components that, although not marked as mandatory, are required by NIH (e.g., the “Credential” log-in field of the “Research & Related Senior/Key Person Profile” component must contain the PD/PI’s assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see “Frequently Asked Questions – Application Guide, [Electronic Submission of Grant Applications](#).”

The SF424 (R&R) application has several components. Some components are required, others are optional. The forms package associated with this FOA in [Grants.gov/APPLY](#) includes all applicable components, required and optional. A completed application in response to this FOA includes the data in the following components:

**Required Components:**

SF424 (R&R) (Cover component)  
Research & Related Project/Performance Site Locations  
Research & Related Other Project Information  
Research & Related Senior/Key Person  
PHS398 Cover Page Supplement  
PHS398 Research Plan  
PHS398 Checklist  
PHS398 Modular Budget or Research & Related Budget: Use only one, as appropriate. (See Section IV.6., “Special Instructions,” regarding appropriate required budget component. Research & Related Budget is required for foreign applications.)

Required & Optional Components

**Optional Components:**

PHS398 Cover Letter File  
Research & Related Subaward Budget Attachment(s) Form

**Foreign Organizations** (Non-domestic (non-U.S.) Entity)

NIH policies concerning grants to foreign (non-U.S.) organizations can be found in the *NIH Grants Policy Statement* at:

[http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part12.htm#\\_Toc54600260](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600260).

Applications from foreign organizations must:

- Request budgets in U.S. dollars.
- Prepare detailed budgets for all applications (that is, complete the Research & Related Budget component of the SF424 (R&R) application forms – not the PHS398 Modular Budget component). See [NOT-OD-06-096](#).
- Charge back of customs and import fees is not allowed.
- Format: Every effort should be made to comply with the format specifications, which are based upon a standard U.S. paper size of 8.5” x 11” within each PDF.
- Funds for up to 8% administrative costs (excluding equipment) may be requested. See [NOT-OD-01-028](#), March 29, 2001.

- Organizations must comply with Federal/NIH policies on human subjects, animals, and biohazards.
- Organizations must comply with Federal/NIH biosafety and biosecurity regulations. See [Section VI.2.](#), “Administrative and National Policy Requirements.”

Proposed research should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.

## **SPECIAL INSTRUCTIONS**

### **Applications with Multiple PDs/PIs**

When multiple PDs/PIs are proposed, NIH requires one PD/PI to be designated as the "Contact" PI, who will be responsible for all communication between the PDs/PIs and the NIH, for assembling the application materials outlined below, and for coordinating progress reports for the project. The contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PDs/PIs, but has no other special roles or responsibilities within the project team beyond those mentioned above.

Information for the Contact PD/PI should be entered in item 15 of the SF424 (R&R) Cover component. All other PDs/PIs should be listed in the Research & Related Senior/Key Person component and assigned the project role of “PD/PI.” Please remember that all PDs/PIs must be registered in the eRA Commons prior to application submission. **The Commons ID of each PD/PI must be included in the “Credential” field of the Research & Related Senior/Key Person component. Failure to include this data field will cause the application to be rejected.**

All projects proposing Multiple PDs/PIs will be required to include a new section describing the leadership of the project.

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, a new section of the research plan, entitled “Multiple PD/PI Leadership Plan” (section 14 of the Research Plan Component in the SF424 [R&R]), must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award.

### **Applications Involving a Single Institution**

When all PDs/PIs are within a single institution, follow the instructions contained in the SF424 (R&R) Application Guide.

### Applications Involving Multiple Institutions

When multiple institutions are involved, one institution must be designated as the prime institution and funding for the other institution(s) must be requested via a subcontract to be administered by the prime institution. When submitting a detailed budget, the prime institution should submit its budget using the Research & Related Budget component. All other institutions should have their individual budgets attached separately to the Research & Related Subaward Budget Attachment(s) Form. See Section 4.8 of the SF424 (R&R) Application Guide for further instruction regarding the use of the subaward budget form.

When submitting a modular budget, the prime institution completes the PHS398 Modular Budget component only. Information concerning the consortium/subcontract budget is provided in the budget justification. Separate budgets for each consortium/subcontract grantee are not required when using the Modular budget format. See Section 5.4 of the Application Guide for further instruction regarding the use of the PHS398 Modular Budget component.

### 3. Submission Dates and Times

See [Section IV.3.A](#) for details.

Standard submission and award dates apply.

#### 3.A. Submission, Review, and Anticipated Start Dates

Opening Date: January 5, 2007 (Earliest date an application may be submitted to Grants.gov)

Application Submission/Receipt Date(s): Standard dates apply, please see

<http://grants.nih.gov/grants/funding/submissionschedule.htm>

AIDS Application Submission/Receipt Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS>

Peer Review Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

Council Review Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

Earliest Anticipated Start Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

#### 3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity.

ELECTRONIC SUBMISSION

#### 3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via

[http://www.grants.gov/applicants/apply\\_for\\_grants.jsp](http://www.grants.gov/applicants/apply_for_grants.jsp) and follow steps 1-4. Note: Applications

must only be submitted electronically. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

### 3.C. Application Processing

Applications **may** be submitted on or after the opening date and **must** be successfully received by Grants.gov no later than **5:00 p.m. local time** (of the applicant institution/organization) on the application submission/receipt date(s). (See [Section IV.3.A.](#) for all dates.) If an application is not submitted by the receipt date(s) and time, the application may be delayed in the review process or not reviewed.

**IMPORTANT!!**

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two business days to view the application image.

- If everything is acceptable, no further action is necessary. The application will automatically move forward for processing by the Division of Receipt and Referral, Center for Scientific Review, NIH, after two business days.
- Prior to the submission deadline, the AOR/SO can “Reject” the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if the AOR/SO determines that warnings should be addressed or if information was lost or compromised during transmission. Reminder: warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two business days if no action is taken. Please remember that some warnings may not be applicable or may need to be addressed after application submission.
- If the two-day window falls after the submission deadline, the AOR/SO will have the option to “Reject” the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn’t transfer correctly during the submission process). The AOR/SO should first contact the [eRA Commons Helpdesk](#) to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/SO chooses to “Reject” the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the [NIH late policy](#) guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment.
- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two days.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Incomplete applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the [Commons](#). The submitting AOR receives the Grants.gov acknowledgments. The AOR and the PI receive

Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

**Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on their application status in the Commons.**

The NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of an application already reviewed with substantial changes, but such application must include an "Introduction" (3 pages maximum) addressing the previous critique. Note such an application is considered a "resubmission" for the SF424 (R&R).

#### 4. Intergovernmental Review

This initiative is not subject to [\*intergovernmental review\*](#).

#### 5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [\*NIH Grants Policy Statement\*](#).

Pre-award costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing renewal (formerly "competing continuation") award if such costs: are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing renewal award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See the [\*NIH Grants Policy Statement\*](#).

#### 6. Other Submission Requirements

**PD/PI Credential (e.g., Agency Login)**

The NIH requires the PD/PI(s) to fill in his/her Commons User ID in the “PROFILE – Project Director/Principal Investigator” section, “Credential” log-in field of the “Research & Related Senior/Key Person Profile” component.

Must fill in Commons User ID in order to successfully get through grants.gov

## Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see “Frequently Asked Questions – Application Guide, [Electronic Submission of Grant Applications](#).”

## PHS398 Research Plan Component Sections

Items 2-5 of the PHS398 Research Plan component are limited to 25 pages. While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts, and with the following additional requirements:

Specific Cost Information on Budgetary mechanism to use

### Special Instructions for Modular Grant applications

R01 applications from U.S. institutions/organizations requesting up to \$250,000 per year in direct costs (excluding consortium F&A costs) must be submitted in a modular budget format. Additional information on modular budgets is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>. When submitting a modular budget, the applicant organization will include only the PHS398 Modular Budget component. See Section 5.4 of the SF424 (R&R) Application Guide for further instructions regarding the use of the PHS398 Modular Budget component. Foreign organizations may not submit modular budgets. See [NOT-OD-06-096](#).

### Special Instructions for Applications Requesting \$500,000 (direct costs) or More Per Year

Applicants requesting \$500,000 or more in direct costs for any year (excluding consortium F&A costs) must carry out the following steps:

- 1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;
- 2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,

3) Include the PHS398 Cover Letter component with the application to identify the staff member and IC who agreed to accept assignment of the application.

This policy applies to all new applications, competing renewal (formerly “competing continuation”) applications, resubmission (formerly “revised/amended”) applications, and revision (formerly “competing supplemental”) applications. See NOT-OD-02-004, October 16, 2001.

### Appendix Materials

**IMPORTANT- Go to SF424 Guidelines-see website below for allowable appendix material**



**IMPORTANT NOTE: NIH has published new limitations on grant application appendix materials to encourage applications to be as concise as possible while containing the information needed for expert scientific review.**

Applicants **must** follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (See <http://grants.nih.gov/grants/funding/424/index.htm>).

Do not use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the required page limitations may be delayed in the review process.

Note: While each section of the PHS398 Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to monitor better formatting requirements such as page limits. All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

### Foreign Applications (Non-domestic (non-U.S.) Entity)

- Indicate how the proposed project has specific relevance to the mission and objectives of the IC and has the potential for significantly advancing the health sciences in the United States.
- Research grant applications from foreign or international organizations may not be funded unless approved by the IC National Advisory Council or Board.

### Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any

conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal Web site, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

Applicants requesting more than \$500,000 in direct costs in any year of the proposed research must include a plan for sharing research data in their application. The funding organization will be responsible for monitoring the data sharing policy ([http://grants.nih.gov/grants/policy/data\\_sharing](http://grants.nih.gov/grants/policy/data_sharing)).

Over \$500K Research Plan Requirement

The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

### Sharing Research Resources

NIH policy expects that grant recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the *NIH Grants Policy Statement*

[http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part7.htm#\\_Toc54600131](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600131)).

Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each [Non-Competing Grant Progress Report \(PHS 2590\)](#). See [Section VI.3](#), "Reporting."

### Section V. Application Review Information

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1. Criteria (**Update:** Enhanced review criteria have been issued for the evaluation of research applications received for potential FY2010 funding and thereafter - see [NOT-OD-09-025](#)).

Only the review criteria described below will be considered in the review process.

#### 2. Review and Selection Process

Applications submitted for this funding opportunity will be assigned to the ICs on the basis of established PHS referral guidelines.

Appropriate scientific review groups convened in accordance with the standard NIH peer review

procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- **Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.**
- **Receive a written critique.**
- **Receive a second level of review by the appropriate national advisory council or board.**

Applications submitted in response to this funding opportunity will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- **Scientific merit of the proposed project as determined by peer review.**
- **Availability of funds.**
- **Relevance of program priorities.**

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application.

- Significance
- Approach
- Innovation
- Investigator
- Environment

Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

**Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? For applications

designating multiple PDs/PIs, is the leadership approach, including the designated roles and responsibilities, governance, and organizational structure, consistent with and justified by the aims of the project and the expertise of each of the PDs/PIs?

**Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?

**Investigators:** Are the PD/PIs and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level(s) of the principal investigator(s) and other researchers? Do the PD/PIs and investigative team bring complementary and integrated expertise to the project (if applicable)?

**Environment:** Do(es) the scientific environment(s) in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

## 2.A. Additional Review Criteria

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

**Resubmission Applications (formerly “revised/amended” applications):** Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

**Protection of Human Subjects from Research Risk:** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. See the “Human Subjects Sections” of the PHS398 Research Plan component of the SF424 (R&R).

**Inclusion of Women, Minorities and Children in Research:** The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. See the “Human Subjects Sections” of the PHS398 Research Plan component of the SF424 (R&R).

**Care and Use of Vertebrate Animals in Research:** If vertebrate animals are to be used in the project, the adequacy of the plans for care and use of vertebrate animals to be used in the project will be assessed. See the “Other Research Plan Sections” of the PHS398 Research Plan component of the SF424 (R&R).

**Biohazards:** If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

## 2.B. Additional Review Considerations

**Budget and Period of Support:** The reasonableness of the proposed budget and the appropriateness of the requested period of support in relation to the proposed research may be assessed by the reviewers. The priority score should not be affected by the evaluation of the budget.

**Applications from Foreign Organizations:** Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources will be assessed.

## 2.C. Sharing Research Data

**Data Sharing Plan:** The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy.

[http://grants.nih.gov/grants/policy/data\\_sharing](http://grants.nih.gov/grants/policy/data_sharing).

## 2.D. Sharing Research Resources

NIH policy expects that grant recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the *NIH Grants Policy Statement*

[http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPs\\_Part7.htm#\\_Toc54600131](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part7.htm#_Toc54600131)).

Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

Program staff will be responsible for the administrative review of the plan for sharing research resources.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each [Non-Competing Grant Progress Report \(PHS 2590\)](#), See [Section VI.3](#), "Reporting."

**Model Organism Sharing Plan:** Reviewers are asked to assess the sharing plan in an administrative note. The sharing plan itself should be discussed after the application is scored. Whether a sharing plan is reasonable can be determined by the reviewers on a case-by-case basis, taking into consideration the organism, the timeline, the applicant's decision to distribute the resource or deposit it in a repository, and other relevant considerations.

### 3. Anticipated Announcement and Award Dates

Not Applicable.

## Section VI. Award Administration Information

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### 1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the NIH eRA [Commons](#).

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See [Section IV.5.](#), "Funding Restrictions."

### 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](#).

### 3. Reporting

When multiple years are involved, awardees will be required to submit the [Non-Competing Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the [NIH Grants Policy Statement](#).

## Section VII. Agency Contacts

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We encourage scientific/programmatic inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. **Reminder: Questions**

concerning electronic submission should be directed to Grants.gov or eRA Commons. See [Section IV](#).

1. Scientific/Research Contacts:

Participating NIH Institutes and Centers are listed on the first page of this announcement (“[Components of Participating Organizations](#)”). Scientific/research contact information is listed in the table below.

NIH Institute/Center	Scientific/Research Contact Information
<a href="#">National Cancer Institute</a>	<a href="http://www.cancer.gov/researchandfunding/contacts">http://www.cancer.gov/researchandfunding/contacts</a> 301-496-3428
<a href="#">National Center for Complementary and Alternative Medicine</a>	<a href="http://nccam.nih.gov/research/contact/index.htm">http://nccam.nih.gov/research/contact/index.htm</a> 301-496-4792
<a href="#">National Center on Minority Health and Health Disparities</a>	<a href="http://ncmhd.nih.gov/">http://ncmhd.nih.gov/</a> 301-402-1366
<a href="#">National Center for Research Resources</a>	<a href="http://www.ncrr.nih.gov/contact_us.asp">http://www.ncrr.nih.gov/contact_us.asp</a> 301-496-6023
<a href="#">National Eye Institute</a>	<a href="http://www.nei.nih.gov">www.nei.nih.gov</a>
<a href="#">National Heart, Lung, and Blood Institute</a>	<a href="http://www.nhlbi.nih.gov/about/staff-expertise.htm">http://www.nhlbi.nih.gov/about/staff-expertise.htm</a>
<a href="#">National Human Genome Research Institute</a>	<a href="http://www.genome.gov/10000884">http://www.genome.gov/10000884</a> 301-496-7531
<a href="#">National Institute on Aging</a>	<a href="http://www.nia.nih.gov/ResearchInformation/ExtramuralPrograms/">http://www.nia.nih.gov/ResearchInformation/ExtramuralPrograms/</a>
<a href="#">National Institute on Alcohol Abuse and Alcoholism</a>	301-443-0281 <a href="http://www.niaaa.nih.gov">www.niaaa.nih.gov</a>
<a href="#">National Institute of Allergy and Infectious Diseases</a>	AIDS: <a href="http://www3.niaid.nih.gov/about/findingpeople/daid.htm">http://www3.niaid.nih.gov/about/findingpeople/daid.htm</a>  Allergy, Immunology, and Transplantation: <a href="http://www3.niaid.nih.gov/about/findingpeople/dait.htm">http://www3.niaid.nih.gov/about/findingpeople/dait.htm</a>  Microbiology and Infectious Diseases: <a href="http://www3.niaid.nih.gov/about/findingpeople/dmid_staff.htm">http://www3.niaid.nih.gov/about/findingpeople/dmid_staff.htm</a>  General Information on NIAID Extramural Grant Programs: <a href="mailto:dart@mail.nih.gov">dart@mail.nih.gov</a>

<a href="#">National Institute of Arthritis and Musculoskeletal and Skin Diseases</a>	<a href="http://www.niams.nih.gov/an/directory/epphone.htm">http://www.niams.nih.gov/an/directory/epphone.htm</a> 301-594-2463
<a href="#">National Institute of Biomedical Imaging and Bioengineering</a>	<a href="http://www.nibib.nih.gov/Research/ProgramAreas">http://www.nibib.nih.gov/Research/ProgramAreas</a>
<a href="#">National Institute of Child Health and Human Development</a>	<a href="http://www.nichd.nih.gov/about/org/orgchart/">http://www.nichd.nih.gov/about/org/orgchart/</a>
<a href="#">National Institute on Deafness and Other Communication Disorders</a>	<a href="#">NIDCD Staff Contacts</a>
<a href="#">National Institute of Dental and Craniofacial Research</a>	<a href="http://www.nidcr.nih.gov/AboutNIDCR/Organization/default.htm">http://www.nidcr.nih.gov/AboutNIDCR/Organization/default.htm</a> 301-594-4800
<a href="#">National Institute of Diabetes and Digestive and Kidney Diseases</a>	<a href="http://www2.niddk.nih.gov/Research/ScientificAreas/">http://www2.niddk.nih.gov/Research/ScientificAreas/</a>
<a href="#">National Institute on Drug Abuse</a>	<a href="http://www.nida.nih.gov">http://www.nida.nih.gov</a>
<a href="#">National Institute of Environmental Health Sciences</a>	<a href="http://www.niehs.nih.gov/dert/pasci.htm">http://www.niehs.nih.gov/dert/pasci.htm</a> 919-541-7723
<a href="#">National Institute of General Medical Sciences</a>	<a href="http://search.nigms.nih.gov/research/programs.htm">http://search.nigms.nih.gov/research/programs.htm</a> 301-594-4499
<a href="#">National Institute of Mental Health</a>	<a href="http://www.nimh.nih.gov/about/ed_chart.cfm">http://www.nimh.nih.gov/about/ed_chart.cfm</a> 301-443-3367
<a href="#">National Institute of Neurological Disorders and Stroke</a>	<a href="http://www.ninds.nih.gov/funding/areas/index.htm">http://www.ninds.nih.gov/funding/areas/index.htm</a> 301-496-9248
<a href="#">National Institute of Nursing Research</a>	<a href="http://ninr.nih.gov/assets/Documents/NINR_StrategicPlan.pdf">http://ninr.nih.gov/assets/Documents/NINR_StrategicPlan.pdf</a> 301-594-6906
<a href="#">National Library of Medicine</a>	<a href="http://www.nlm.nih.gov/ep/GrantResearch.html">http://www.nlm.nih.gov/ep/GrantResearch.html</a> 301-594-4882

2. Peer Review Contacts:

Not applicable

3. Financial/Grants Management Contact(s):

See participating NIH Institutes and Centers listed on the first page of this announcement (“[Components of Participating Organizations](#)”).

Section VIII. Other Information

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## Required Federal Citations

### **Use of Animals in Research:**

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable.

### **Human Subjects Protection:**

Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

### **Data and Safety Monitoring Plan:**

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (“NIH Policy for Data and Safety Monitoring,” *NIH Guide for Grants and Contracts*, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

### **Sharing Research Data:**

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible ([http://grants.nih.gov/grants/policy/data\\_sharing](http://grants.nih.gov/grants/policy/data_sharing)).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

### **Access to Research Data through the Freedom of Information Act:**

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm). Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If

so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

### **Sharing of Model Organisms:**

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see [http://grants.nih.gov/grants/policy/model\\_organism/index.htm](http://grants.nih.gov/grants/policy/model_organism/index.htm)). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the [NIH Grants Policy Statement](#)). Beginning October 1, 2004, all investigators submitting an NIH application or contract proposal are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

### **Inclusion of Women And Minorities in Clinical Research:**

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the SF424 (R&R) application; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

### **Inclusion of Children as Participants in Clinical Research:**

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects

<http://grants.nih.gov/grants/funding/children/children.htm>).

**Required Education on the Protection of Human Subject Participants:**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

**Human Embryonic Stem Cells (hESC):**

Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov/>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

**NIH Public Access Policy:**

NIH-funded investigators are requested to submit to the NIH manuscript submission (NIHMS) system (<http://www.nihms.nih.gov/>) at PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process.

NIH is requesting that authors submit manuscripts resulting from 1) currently funded NIH research projects or 2) previously supported NIH research projects if they are accepted for publication on or after May 2, 2005. The NIH Public Access Policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The Policy applies to peer-reviewed, original research publications that have been supported in whole or in part with direct costs from NIH, but it does not apply to book chapters, editorials, reviews, or conference proceedings. Publications resulting from non-NIH-supported research projects should not be submitted.

For more information about the Policy or the submission process, please visit the NIH Public Access Policy Web site at <http://publicaccess.nih.gov/> and view the Policy or other Resources and Tools, including the [Authors' Manual](#).

**Standards for Privacy of Individually Identifiable Health Information:**

The Department of Health and Human Services (HHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

### **URLs in NIH Grant Applications or Appendices:**

All applications and proposals for NIH funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, Internet addresses (URLs) or PubMed Central (PMC) submission identification numbers must be used for publicly accessible on-line journal articles. Publicly accessible on-line journal articles or PMC articles/manuscripts accepted for publication that are directly relevant to the project may be included **only** as **URLs** or **PMC submission identification numbers** accompanying the full reference in either the Bibliography & References Cited section, the Progress Report Publication List section, or the Biographical Sketch section of the NIH grant application. A URL or PMC submission identification number citation may be repeated in each of these sections as appropriate. There is no limit to the number of URLs or PMC submission identification numbers that can be cited.

### **Healthy People 2010:**

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

### **Authority and Regulations:**

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

### **Loan Repayment Programs:**

NIH encourages applications for educational loan repayment from qualified health professionals

who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: <http://www.lrp.nih.gov/>.

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